Attachment 4

510(k) Summary

[As Required by 21 CFR 807.92]

OCT - 8 2009

Date Prepared: September 08, 2009

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Trade Name: Body Composition Analyzer Model ioi 353
Common Name: Body Fat Analyzer / Body Fat Monitor / Body Composition Monitor
Classification Name: Body Composition Analyzer (Impedance plethysmograph) / MNW
Predicate Device: Body Composition Analyzer Models GAIA 359 PLUS and XBIA 500 (K071884)

Device Description: The ioi 353 is body composition analyzer is intended for use only in healthy subjects between the age of 7-89. The device employs BIA(Bio-electrical Impedance Analysis) method and 8 electrodes placed on hands and feet, and then measure body composition using an experimentally derived algorithm. The device is powered by AC adapter.

Intended use: This device is intended to estimate PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), TBW(Total Body Water), BMI(Body Mass Index), BMR(Basic Metabolic Rate), Segmental LBM, ICW(Intra-Cellular Water), ECW(Extra-Cellular Water), and ratio of ECW/TBW using the BIA(Bio-electrical Impedance Analysis) method. The device measures or calculates the impedance, BMI(Body Mass Index), weight, and WHR(Waist to

Hip Ratio) of the user.
This device is intended for use only in healthy subjects between the age of 7-89.

Technologic characteristics: Modified device ioi 353 has the same intended use and technology characteristics as predicate device GAIA 359 PLUS or XBIA 500. The differences in this submission don't raise new questions concerning either safety or effectiveness.

Non-clinical and clinical tests: Modified device ioi 353 meets the requirements of IEC 60601-1, EN 60601-1-2 and in-house test criteria. The ioi 353 was not clinically tested because the ioi 353 measures/outputs/determines the same quantities, uses the same frequencies, and uses the same electrode pattern and number of electrodes as the GAIA 359 PLUS.

Conclusions: Based on non-clinical tests, the modified device ioi 353 is as safe, as effective, and perform as well as the predicate device GAIA 359 PLUS or XBIA 500. Accordingly the modified devices are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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c/o Mr. H. L. Jung
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REPUBLIC OF KOREA

OCT - 8 2009

Re: K092431
Trade/Device Name: Jawon Medical Body Composition Analyzer Model ioi 353
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: September 8, 2009
Received: September 14, 2009

Dear Mr. Jung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1

Indications for Use Statement

510(k) Number (if known): K092431

Device Name: Jawon Medical Body Composition Analyzer Model ioi 353

Indications for Use:

This device is intended to estimate PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), TBW(Total Body Water), BMI(Body Mass Index), BMR(Basic Metabolic Rate), Segmental LBM, ICW(Intra-Cellular Water), ECW(Extra-Cellular Water), and ratio of ECW/TBW using the BIA(Bio-electrical Impedance Analysis) method. The device measures or calculates the impedance, BMI(Body Mass Index), weight, and WHR(Waist to Hip Ratio) of the user.

This devices is intended for use only in healthy subjects between the age of 7-89.

Prescription Use ____ AND/OR Over-The-Counter Use ✓
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092431